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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/860,231	07/25/97	THOREL	J	WPB-39818

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EXAMINER
WITZ,J

ART UNIT	PAPER NUMBER
1651	14

DATE MAILED: 01/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/860,231	Applicant(s) Thorel et al.
	Examiner Jean C. Witz	Group Art Unit 1651

☒ Responsive to communication(s) filed on *Nov 2, 1998*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *19-69* is/are pending in the application.

Of the above, claim(s) *22, 39, and 42* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *19-21, 23-38, 40, 41, and 43-69* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *8 & 10*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 19-21, 23-38, 41 and 42 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the invention of Group I is generic to the species of Group II and that the special technical feature that the three Groups have in common is a composition that does not comprise a biological extract of animal or cellular origin, or a living, nourishing substrate. This is not found persuasive because the composition of Group I requires only "at least some amino acids, a vitamin, a cell growth factor, and an inorganic salt" while the composition of Group II requires 20 amino acids in specific amounts, 14 vitamins and cell growth factors, and 15 inorganic salts along with several other components; therefore, the two compositions clearly comprise different compositions. Further, claims in Group I recite merely classes of nutrient media components but do not recite the components themselves. Therefore, there does not appear to be any defined components of the composition of Group I which provide a special technical feature in common with those of the composition of Group II. Also, Applicants' assertions that the special technical feature of the three Groups is what is NOT present, i.e. that the composition is serum-free and contains no accessory cells such as fibroblasts, is not found persuasive as serum-free nutrient media is well known in the art for a broad range of cell types; therefore, such a designation is too broad and fails to act as a special technical feature

to link the compositions of Groups I and II. The claims of Group III, however, will be merged with Group I and examined in this office action.

The remaining requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 19-21, 23-38, 40-41, 44-66 and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindenbaum (5,461,030 or 5,591,709).

The claims are drawn to compositions and methods of medicinal or cosmetic treatment comprising a composition defined as a complex nutrient medium that permits viable in vitro growth of human epidermal keratinocytes with at least one clonal proliferation of said keratinocytes in the first passage and at least one additional component, wherein said composition does not comprise any biological extract of animal or cellular origin or a living, nourishing substrate. It is noted at page 1, lines 23-24, of the specification that Applicants define "biological

extract of animal or cellular origin" as comprising fetal calf serum and at lines 30-31 of the specification, "living, nourishing substrate" as comprising a cellular feeder culture, such as fibroblasts.

Lindenbaum discloses formulations and methods for treating wounds comprising an effective amount of a serum-free cellular nutrient medium in combination with at least one cellular growth stimulating compound. Particularly, Lindenbaum discloses the use of MCDB 153 combined with either human growth hormone, hydrocortisone and/or insulin/transferrin in a delivery polymer. MCDB 153 is a serum-free medium which is known to provide clonal growth of human epidermal keratinocytes. Therefore, the references are deemed to meet each and every limitation of the claims as MCDB 153 is a complex nutrient medium that permits viable in vitro growth of human epidermal keratinocytes with at least one clonal proliferation of said keratinocytes in the first passage containing at least some amino acids, a vitamin, a cell growth factor and an inorganic salt, it is serum-free and does not require a cellular feeder layer, i.e. does not comprise any biological extract of animal or cellular origin or a living, nourishing substrate and is combined with at least one additional component and the composition will permits viable in vitro growth of human epidermal keratinocytes with at least one clonal proliferation of said keratinocytes in the first passage. Recitations of intended use, such as to cosmetic or graft preservation use, fail to impart patentability to an old composition.

4. Claims 19, 24-27, 34, 37, 40-41, 43-44, 46, 48-51, 61, 65-67 and 69 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Wille, Jr. (5,686,307 or 5,292,655).

Wille, Jr. discloses methods and formulations for the in vitro formation of human epidermis in a serum free and companion cell or cell feeder layer-free medium. In Example 3, the medium, identified as HECK-109, is used to achieve clonal growth from individual keratinocytes.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 19-21, 23-38, 40-41 and 43-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of the Lindenbaum patents and the Wille, Jr. patents in view of Cuca.

Lindenbaum teaches that any other serum free nutrient media may be used in the invention. See col. 5, lines 30-50 of 5,461,030. Further, as stated previously, Lindenbaum explicitly teaches the use of the media as a topical composition and teaches the use of a delivery polymer. Wille, Jr. teaches the compositions of his invention have applications as products for the abolition and/or prevention of wrinkles and for the use of autologously-derived cells for transplantation in the treatment of burns or other trauma.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the claimed composition in a manner well known in the art, i.e. two phase topical emulsion, for the purpose of topical administration to human skin, either in the treatment of wounds per Lindenbaum, in the cosmetic treatment of wrinkled skin, per Wille, Jr. or in the treatment of skin grafts, per Wille, Jr.

7. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on Monday through Thursday from 8:00 to 5:30. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEAN C. WITZ
PRIMARY EXAMINER